



Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

1
Manitoba Court
Declares Formulary
Listing for
Apo-Omeprazole
Ultra Vires

Recent Court
Decisions

5
New Court
Proceedings

Manitoba Court Declares Formulary Listing for Apo-Omeprazole *Ultra Vires*

On June 23, 2005, a Manitoba Judge declared that *Manitoba Drug Interchangeability Formulary Regulation 74/2004*, which listed Apo-Omeprazole in the Manitoba formulary as fully interchangeable with LOSEC, was *ultra vires* the regulation-making power of the Minister of Health of the Province of Manitoba ("Manitoba Minister") under *The Pharmaceutical Act* (*AstraZeneca v. Manitoba (Minister of Health) and Apotex*).

Apotex received its notice of compliance (NOC) on January 28, 2004 but, unlike LOSEC, Apo-Omeprazole was not approved federally for the treatment of *H. pylori*. Nevertheless, the Manitoba Minister approved a regulation making Apo-Omeprazole interchangeable with LOSEC for all indications, including the treatment of *H. pylori*. There was evidence that pharmacists were substituting Apo-Omeprazole for LOSEC when filling prescriptions for the treatment of *H. pylori*, even following several reminders to pharmacists that Apo-Omeprazole was not indicated for this treatment.

The Judge found that Apo-Omeprazole did not qualify for listing on the formulary as interchangeable with LOSEC on an unrestricted basis because it is not legally fully interchangeable with LOSEC. He rejected the argument made by the Manitoba Government and Apotex that the only requirement for a designation of interchangeability is that the drugs be scientifically interchangeable because they have same or similar ingredients.

This decision highlights the necessity for restricted formulary listings where a generic product is not approved for all of the innovator's indications. As shown in this case, where a formulary permits full interchangeability, infringement of "use" patents does occur, even though (i) a generic manufacturer's product monograph does not list the patented use as an approved indication, and (ii) pharmacists are specifically notified of this limited approval.

Nancy P. Pei

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Pfizer v. Apotex (**sildenafil (VIAGRA)**), May 12, 2005

A Prothonotary had granted Apotex an extension of time to serve evidence, extended the statutory stay for the period of the extension, and ordered that Apotex is prevented from claiming any loss pursuant to section 8 of the *Regulations* for the period of the extension. Judge allows Apotex's appeal, finding that the Court is without jurisdiction to invoke its powers on its own motion to shorten or extend the statutory stay or to limit damages under subsection 8(5).

Motions Judge's Decision

Prothonotary's Decision (2005 FC 545)

GlaxoSmithKline v. Canada (Minister of Health) (paroxetine hydrochloride (PAXIL CR)), May 24, 2005

Court of Appeal dismisses GSK's appeal of a Judge's decision, upholding the Minister's refusal to list two of GSK's patents on the Patent Register. The claims of the patents do not explicitly claim the medicine at issue, paroxetine hydrochloride. The majority finds that the claims in the patents for controlled release of "active substances" give no guidance "for the medicine itself" and are too imprecise. The minority finds that if the patent protects the delivery system, then it does not contain a claim for the medicine itself or the use of the medicine, even if it refers to a medicine.

Court of Appeal Decision (2005 FCA 197)

Applications Judge's Decision (2004 FC 1725)

Merck v. Apotex (alendronate monosodium trihydrate (FOSAMAX)), May 26, 2005

Court dismisses Merck's application for an Order prohibiting the Minister from issuing an NOC to Apotex. Apotex had alleged invalidity. Court finds that the claimed invention was obvious and lacked utility or a sound prediction of utility.

Full Judgment (2005 FC 755)

Janssen-Ortho v. Canada (Minister of Health) (norelgestromin/ethinyl estradiol transdermal system (EVRA)), May 30, 2005

Court dismisses Janssen-Ortho's application for judicial review of the Minister's refusal to add Janssen-Ortho's patent to the Patent Register. One of the claims at issue reads:

44. A use of an ovulation inhibiting amount of 17-deacetyl norgestimate an estrogen for preventing ovulation in a woman where in the 17-deacetyl norgestimate and the estrogen are co-administered transdermally to the woman from a matrix comprising a mixture of 17-deacetyl norgestimate, and estrogen in a pressure sensitive adhesive comprising at least one of the silicone and polyisobutylene.

Janssen-Ortho had submitted that the claims at issue were claims to the use of the medicine, while the Minister submitted that the pith and substance of the invention is not the medicine or its use, but the delivery or administration of the medicine via a transdermal patch. Judge finds that on the Minister's construction of the claims, Janssen-Ortho could not succeed because "the Courts have repeatedly recognized that a patent construed as claiming a device used to administer a substance does not constitute a claim for the medicine itself or for the use of that medicine". Janssen-Ortho has appealed.

Full Judgment (2005 FC 765)

Apotex v. AB Hassle (omeprazole magnesium (LOSEC)), June 1, 2005

Court of Appeal denies the Canadian Generic Pharmaceutical Association leave to intervene in Apotex's appeal of a Judge's decision, granting an Order of prohibition. The CGPA sought to intervene with respect to the Judge's findings that Apotex was precluded – by reasons of abuse of process, *res judicata* and/or issue estoppel – from alleging non-infringement and invalidity of the patent at issue.

Court of Appeal Decision (2005 FCA 209)

Applications Judge's Decision (2005 FC 234)

AstraZeneca v. Apotex (omeprazole (LOSEC)), June 7, 2005

Court of Appeal dismisses AstraZeneca's appeal of the dismissal of its application for a prohibition Order. AstraZeneca argued that the Judge erred in law in concluding that the notice of allegation (NOA) was not deficient, and that the Judge should have concluded that the allegation of non-infringement was not justified.

Court of Appeal Decision (2005 FCA 216)

Applications Judge's Decision (2004 FC 647)

Apotex v. The Queen and Bristol Myers Squibb (pravastatin (PRAVACHOL, APO-PRAVASTIN)), June 9, 2005

A Prothonotary, affirmed on appeal, had ordered Apotex to answer certain questions refused on discovery in an action for damages pursuant to section 8 of the *Regulations*. Court of Appeal reverses the ruling with respect to one category of questions.

Court of Appeal Decision (2005 FCA 217)

Motions Judge's Decision (2004 FC 1220)

Other Proceedings

Apotex v. Eli Lilly and Shionogi (cefaclor (APO-CEFACLOR, CECLOR)), May 27, 2005

Court of Appeal grants the Commissioner of Competition leave to intervene in Apotex's appeal of a summary judgment decision, striking out portions of Apotex's defence and counterclaim in a patent infringement action brought by Lilly. The Court also struck the counterclaim against Shionogi. The Judge rejected Apotex's allegation that the assignment of Shionogi's patents to Lilly constituted a criminal conspiracy contrary to the *Competition Act*.

Court of Appeal Decision (2005 FCA 203)

Motions Judge's Decision (2004 FC 1445)

Canada (Ministre de Santé) v. Merck (montelukast sodium (SINGULAIR)), June 7, 2005

A Judge had allowed Merck's application for judicial review of Health Canada's decision that certain portions of documents relating to the review of the new drug submission for SINGULAIR would be disclosed pursuant to an *Access to Information Act* request. Court of Appeal allows Minister of Health's appeal. The Court rejects the Applications Judge's approach to determining whether certain information from Merck's SINGULAIR new drug submission (NDS) was confidential. The Court indicates that once the information forms part of the public domain, it can no longer be considered confidential, even if the form in which the information exists is different. In addition, the Court concludes that reviewer's notes and correspondence between the parties is not confidential for the sole reason that they were part of the review process initiated by Merck.

Court of Appeal Decision (in French) (2005 CAF 215)

Applications Judge's Decision (2004 FC 959)

Aventis v. Novopharm (enoxaparin sodium (LOVENOX)), June 7, 2005

Novopharm received its NOC for a generic version of LOVENOX ("Novo-enoxaparin") on February 28, 2005, and Aventis has commenced an action for patent infringement against Novopharm. Judge dismisses Aventis' motion for an interlocutory or interim injunction to restrain Novopharm from, among other things, selling Novo-enoxaparin pending trial. Judge finds that Aventis failed to demonstrate that it will suffer irreparable harm if an injunction is not issued. Aventis has appealed.

Full Judgment (2005 FC 815)

Apotex v. Plantex USA and Teva (gemfibrozil) May 11, 2005

Ontario Court strikes out Apotex's claims of conspiracy and unlawful interference with economic interests in a breach of contract action relating to an agreement to supply gemfibrozil to Apotex for the manufacture of gemfibrozil drug products for sale in United States.

Full Judgment

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine: **sildenafil (VIAGRA)**
Applicants: Pfizer Canada Inc and Pfizer Ireland Pharmaceuticals
Respondents: Apotex Inc and The Minister of Health
Date Commenced: April 22, 2005
Comment: Application for Order of prohibition until expiry of Patent No. 2,163,446. Apotex alleges non-infringement and invalidity.

Medicine: **paclitaxel injection (TAXOL)**
Applicant: Bristol-Myers Squibb Canada Co
Respondents: Parkash Gill and Mayne Pharma (Canada) Inc
Date Commenced: May 10, 2005
Comment: Application for Order of prohibition until expiry of Dr. Gill's Patent No. 2,189,916. Mayne alleges non-infringement.

Medicine: **clarithromycin (BIAXIN BID)**
Applicant: Abbott Laboratories and Abbott Laboratories Limited
Respondents: Ratiopharm, A Division of Ratiopharm Inc and The Minister of Health
Date Commenced: May 27, 2005
Comment: Application for Order of prohibition until expiry of Patents Nos. 2,419,729 and 2,471,102. Ratiopharm alleges non-infringement and invalidity.

Medicine: **azithromycin (ZITHROMAX)**
Applicants: Pfizer Canada Inc and Pfizer Inc
Respondents: RhoxalPharma Inc and The Minister of Health
Date Commenced: June 10, 2005
Comment: Application for Order of prohibition until expiry of Patent No. 1,314,876. RhoxalPharma alleges non-infringement.

Medicine: **omeprazole (LOSEC)**
Applicants: AstraZeneca AB, AB Hassle and AstraZeneca Canada Inc
Respondents: Apotex Inc and The Minister of Health
Date Commenced: June 17, 2005
Comment: Application for Order of prohibition until expiry of Patents Nos. 2,025,668 and 2,133,762. Apotex alleges non-infringement and invalidity.

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Medicine: celecoxib (CELEBREX)

Applicants: GD Searle & Co and Pfizer Canada Inc

Respondents: Novopharm Limited and The Minister of Health

Date Commenced: June 21, 2005

Comment: Application for Order of prohibition until expiry of Patents Nos. 2,177,576 and 2,267,186. Novopharm alleges non-infringement and invalidity ('576 patent) and non-infringement ('186 patent).

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